

INTERNAL AUDITS, THE AUDITOR

Introduction

There are requirements to perform internal audits in almost all quality management standards e.g. ISO 9001 [1], ISO/IEC 17020 [2] and ISO/IEC 17025 [3]. But the requirements on the auditors are rather limited in all these standards. In this Cook Book the role of the internal auditor is discussed. In ISO 19011 [4] internal audits as well as requirements on internal auditors are described in more detail.

Mandate of the auditor

Internal audits shall be planned activities. It is important that audits be ordered by the top management of the laboratory. The internal auditor should have a clear mandate and the whole process of the internal audits, including handling of non-compliances and the mandate of the internal auditor, should be clear to all involved parties. Mandate for the auditors, handling of non-compliances and other important issues concerning the internal audits should be described in a document in the quality management system.

One of the main differences between internal and external audits is the possibility for the internal auditor to be much more helpful in the laboratory's work with continuous improvements compared to an external auditor whose influence is much more restricted. And that opportunity must be taken by the internal auditor to make the internal audits as valuable as possible for the organisation.

The independence of the auditor

In the normal case, an internal auditor from another department is chosen to assure the independence of an auditor. But if the laboratory has few employees the requirements for independence of the auditor may be a problem. It is allowed to use an internal auditor belonging to the department when the laboratory is small, e.g. less than 10 employees. It is however important that an auditor shall not audit her/his own work.

When internal auditors who are not members of the organisation are used the question of independence is no longer relevant. For small laboratories, a combination of internal auditors belonging to the organisation and internal auditors not belonging to the organisation (consultants) may be a good solution. E.g. use a consultant for a least one of the internal audits during an accreditation cycle.

Confidence in the auditor

Even though the auditor is acting upon a mandate from the top management of the laboratory the auditor should, if possible, try to avoid identifying co-workers interviewed during the audit when reporting especially if the information provided by the co-worker is negative. Otherwise the auditor could have problems to perform the audit in a way leading to real improvements of the activities of the laboratory.

The competence, training and qualification of the auditor

The top management of the laboratory can order the internal audits and might also preferably point to what the internal audits has to focus on. The needed competence of the internal auditor is decided by the management ordering the audits. In other words, it is possible that an auditor may be competent for some type of audits but not for others.

Even though the specific audit is deciding the needed competence of the auditor, it is reasonable to ask for some basic requirements on the auditor:

- knowledge about the requirement documents, normally ISO/IEC 17025, accreditation guidelines and in some cases ISO 9001. There may also be a need to be aware of documents including requirements from voluntary and regulatory schemes;
- knowledge about the audited activities, even though a different background may lead to interesting and good findings during an audit, in the normal situation an auditor with good knowledge about the technical area she/he is auditing is to be preferred in most of the internal audits during an accreditation cycle; and
- training in auditing technique, e.g. by participation in training courses but it also possible to be trained in auditing by following an experienced internal auditor during some audits.

Personal skills and attitude of the auditor

The internal auditor may:

- not act as a policeman,
- not act as a buddy,
- be discussion partner,
- be aware that the personnel that are audited usually are nervous and uncomfortable about the situation, and
- try to help and improve and at the same time keep a reasonable level of independence.

Advice to the auditor

- remember to introduce yourself to all personnel you are interviewing,
- do not ask for the impossible, the normal activities of the organisation must go on,
- be aware that not all people can answer all questions,
- be active, do not let interviewed persons lead the audit, but on the other hand you have to listen to and let the interviewed persons finish,
- do not get stuck in papers and documents but audit the real activities of the organisation,
- keep the focus on important issues and do not get lost in details,
- interview many persons,
- take clear notes all the time; it is hard to remember what was discussed in the early morning when you are writing the report in the evening,
- “sell” non-compliances, it is important that the non-compliances are understood and accepted by the audited organisation and the personnel,
- pick random samples, do not check everything,
- try to verify and search for evidence, do not search for faults,
- give advice and search for improvements,
- keep the time schedule, if you are getting late, inform the persons waiting,
- think about secrecy and independence, the personnel interviewed must be sure that the auditor, if it is possible, is not revealing the source of criticism, on the other hand the internal auditor is acting on the mandate and order of the management, and
- do not follow checklists too strictly, it is important to be able to improvise

Mandate and handling of non-compliances

It is very important to decide the mandate of the auditor before the audit starts. This is the responsibility of the top management. It is also important to stress that the internal auditor is not responsible for handling non-compliances. That is the responsibility of the management of the audited organisation.

References

- [1] ISO 9001:2015. “Quality Management Systems – Requirements”
- [2] ISO/IEC 17020:2012. “Requirements for the operation of various types of bodies performing inspection”
- [3] ISO/IEC 17025:2017, “General requirements for the competence of testing and calibration laboratories”
- [4] ISO 19011:2002. “Guidelines for quality and/or environmental management systems auditing”

See also

- Cook Book no. 9 Internal audits
- Cook Book no. 14: Internal audits, audit report